ACID REDUCER ORIGINAL STRENGTH- famotidine tablet ACID REDUCER MAXIMUM STRENGTH- famotidine tablet Dr.Reddys Laboratories Inc.

Dr.Reddy's Laboratories Limited

Active ingredient (in each tablet)

Famotidine USP, 10 mg/20 mg

Purpose

Acid reducer

Uses

- relieves heartburn associated with acid indigestion and sour stomach
- prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain food and beverages

Warnings

Allergy alert: Do not use if you are allergic to famotidine or other acid reducers

Do not use

- if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
- with other acid reducers

Ask a doctor before use if you have

- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with **lightheadedness**, **sweating**, **or dizziness**
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent chest pain
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain
- kidney disease

Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.

Stop use and ask a doctor if

- your heartburn continues or worsens
- you need to take this product for more than 14 days

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

- For Famotidine 10 mg:
- adults and children 12 years and over:
 - to **relieve** symptoms, swallow 1 tablet with a glass of water. Do not chew.
 - to **prevent** symptoms, swallow 1 tablet with a glass of water at any time from **15 to 60 minutes before** eating food or drinking beverages that cause heartburn
 - do not use more than 2 tablets in 24 hours
- children under 12 years: ask a doctor
- For Famotidine 20 mg:
- adults and children 12 years and over:
 - to **relieve** symptoms, swallow 1 tablet with a glass of water. Do not chew.
 - to **prevent** symptoms, swallow 1 tablet with a glass of water at any time from **10 to 60 minutes before** eating food or drinking beverages that cause heartburn
 - do not use more than 2 tablets in 24 hours
- children under 12 years: ask a doctor

Other information

- read the directions and warnings before use
- keep the carton. It contains important information.
- store at 20°-25°C (68°-77°F)
- protect from moisture and light

Inactive ingredients

colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch, synthetic red iron oxide (only in 10 mg), talc and titanium dioxide

Questions or comments?

call 1-888-375-3784

Tips For Managing Heartburn

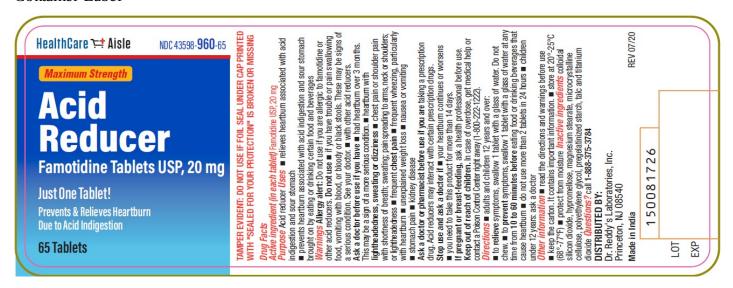
Tips for Managing Heartburn

- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the stomach
- Do not eat before bedtime
- Raise the head of your bed
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking

Principal Display Panel

Famotidine 20 mg

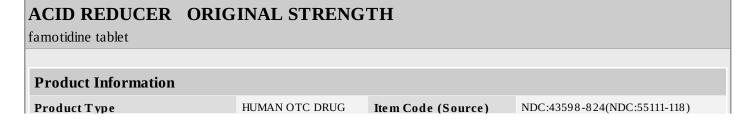
Container Label



Principal Display Panel

Famotidine 20 mg Container Carton Label





Route of Administration

ORAL

Active Ingredient/Active Moiety	Active	Ingredient/	Active	Moietv
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	Ingredient Name	Basis of Strength	Strength
	FAMO TIDINE (UNII: 5QZO15J2Z8) (FAMOTIDINE - UNII:5QZO15J2Z8)	FAMOTIDINE	10 mg

Inactive Ingredients				
Ingredient Name	Strength			
MAGNESIUM STEARATE (UNII: 70097M6I30)				
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)				
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
STARCH, CORN (UNII: O8232NY3SJ)				
Polyethylene Glycol, Unspecified (UNII: 3WJQ0SDW1A)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)				
FERRIC OXIDE RED (UNII: 1K09F3G675)				

Product Characteristics					
Color	WHITE	Score	no score		
Shape	ROUND	Size	6mm		
Flavor		Imprint Code	C;118		
Contains					

l	Packaging					
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
l	1 NDC:43598-824-18	1 in 1 CARTON	09/01/2020			
l	1	180 in 1 BOTTLE; Type 0: Not a Combination Product				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA077367	09/01/2020		

ACID REDUCER MAXIMUM STRENGTH

famotidine tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43598-960(NDC:55111-396)
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
FAMO TIDINE (UNII: 5QZO 15J2Z8) (FAMOTIDINE - UNII:5QZO 15J2Z8)	FAMOTIDINE	20 mg		

Inactive Ingredients			
Ingredient Name	Strength		
MAGNESIUM STEARATE (UNII: 70097M6I30)			
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)			
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)			
HYPROMELLOSES (UNII: 3NXW29V3WO)			
STARCH, CORN (UNII: O8232NY3SJ)			
Polyethylene Glycol, Unspecified (UNII: 3WJQ0SDW1A)			
TALC (UNII: 7SEV7J4R1U)			
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)			

Product Characteristics					
Color	WHITE	Score	no score		
Shape	ROUND	Size	8 mm		
Flavor		Imprint Code	L1		
Contains					

Pa	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:43598-960-65	1 in 1 CARTON	09/01/2020			
1		65 in 1 BOTTLE; Type 0: Not a Combination Product				
2	NDC:43598-960-32	1 in 1 CARTON	09/01/2020			
2		170 in 1 BOTTLE; Type 0: Not a Combination Product				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA077367	09/01/2020		

Labeler - Dr.Reddys Laboratories Inc. (802315887)

Revised: 8/2020 Dr.Reddys Laboratories Inc.